IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SURGIQUEST, INC., Plaintiff, v. LEXION MEDICAL, LLC, Defendant.	C.A. No. 14-382-GMS **JURY TRIAL DEMANDED**

SUPPLEMENTAL AND AMENDED COMPLAINT

SurgiQuest, Inc. ("Plaintiff") as and for its Supplemental and Amended Complaint against Lexion Medical, LLC ("Defendant"), states and alleges as follows:

PARTIES

1. Plaintiff is a Delaware corporation with its principal place of business at 333 Quarry Road, Milford, CT 06460.

2. Defendant is a Delaware limited liability company registered in Minnesota as a foreign limited liability company with its principal place of business at 545 Atwater Circle, St. Paul, MN 55103.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over the claims asserted in this action pursuant to 28 U.S.C. §§ 1331, 1338, and 1367, in that Plaintiff seeks, *inter alia*, relief for Defendant's false and misleading advertising under the Lanham Act and a declaratory judgment that Plaintiff's conduct does not violate the Lanham Act by virtue of its marketing, promotion and sales of its AirSeal® system for use in laparoscopic surgery. Plaintiff also seeks relief for Defendant's violations under Delaware state law.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendant is a Delaware limited liability company.

FACTS

5. Plaintiff is a medical device company that manufactures, offers for sale, and sells the AirSeal® system used in laparoscopic surgery.

6. Defendant is a medical device company that manufactures, offers for sale, and sells the Insuflow® device and the Synergy® device used in laparoscopic surgery.

7. Plaintiff and Defendant are competitors in the area of surgical laparoscopic devices.

8. Laparoscopic surgery requires a small incision through which a hollow tube (called a trocar or cannula) is inserted into the body. A laparoscope and/or other instruments are passed through the cannula into the body in order to perform certain functions.

9. During laparoscopic surgery, the abdominal wall is elevated above the organs with "insufflation gas" (usually carbon dioxide) to increase working space and visibility. Occasionally, insufflation gas diffuses into the subcutaneous tissue, traveling to other parts of the body and leading to a condition known as "subcutaneous emphysema," *i.e.*, puffiness or bloating, that typically resolves without harm to the patient. Such incidents may occur regardless of the type of insufflation system used.

10. In traditional systems - such as that manufactured by Defendant - an insufflator supplies gas under pressure to the abdomen to keep the abdomen inflated. To prevent this gas from escaping the abdominal cavity through the cannula, the cannula has traditionally included one or more one-way valves through which all instruments must pass. But the insufflation gas

leaks (for example, as instruments pass through the valves), so more gas must be regularly pumped into the abdominal cavity.

11. The use of such valves in these older-style systems presents several problems aside from gas leakage.

12. For example, the lens of the laparoscope (which enables doctors to see inside the abdominal cavity) often becomes blurred, reducing visibility, when it is passed through the valves. And instruments and/or specimens are often trapped by the valves as they are being withdrawn from the body.

13. Plaintiff, however, makes and sells a revolutionary new system - the AirSeal® system - that eliminates the one-way valves needed in older technology (including that of Defendant).

14. Plaintiff's AirSeal® system is safe, effective, and FDA-cleared.

15. Indeed, when Defendant sought FDA clearance to market one of its products, it represented to the FDA that its product was "substantially equivalent" to another "safe and effective" product previously approved by the FDA - SurgiQuest's AirSeal®. (Two of those filings are annexed hereto as **Exhibit A**.)

16. AirSeal® uses a constant flow of gas to achieve the desired intra-abdominal pressure. Then, the system establishes a horizontal air barrier inside the cannula, without any mechanical closure. The result is that the cannula is an unobstructed open tube through which laparoscopes and surgical instruments may be passed without impediment - yet the insufflation gas does not escape in meaningful quantities.

17. Plaintiff's AirSeal® system constantly re-circulates and filters the gas, without the need to introduce large amounts of additional gas. Intra-abdominal pressure is automatically sensed and maintained through real-time sensors in the AirSeal® system.

18. Lexion claims that insufflation gas should be warmed and humidified (which it calls "conditioning") to prevent certain side effects from the constant introduction of cold, dry gas. Plaintiff, however, does not separately heat or humidify the gas, since (unlike older systems) its system does not cause meaningful cooling or drying of the intra-abdominal environment.

19. Plaintiff markets the AirSeal® system principally on the basis of the benefits of providing valve-free access to the abdominal cavity, stable pneumoperitoneum, and continuous smoke evacuation (the smoke created by some laparoscopic procedures that involve burning of tissue clouds the camera lens, and it poses health risks to operating room staff if inhaled).

20. Defendant markets its competing devices to surgeons, nurses, and hospitals throughout the United States, including upon information and belief, those in the state of Delaware.

21. Incident reports filed about Defendant's device show that over the past several years, the Insuflow® device has been the subject of numerous adverse event reports. (Copies of several of those reports are annexed hereto as **Exhibit B**.) Those reports indicate that Defendant's product has an ongoing problem of overheating and sending smoke into the patient's abdomen. This problem has apparently persisted for years.

22. In or about September, 2013, Defendant Lexion commenced an action against Plaintiff SurgiQuest in federal court in the District of Minnesota alleging violations of the Lanham Act together with related Minnesota state law claims.

23. As part of that lawsuit Defendant Lexion claimed that SurgiQuest had engaged in false advertising because it states in its marketing collateral that conditioning insufflation gas is unnecessary with the AirSeal® system. However, SurgiQuest has not engaged in any false advertising and denies the allegations Lexion made against it in that litigation.

24. In or about December, 2013, SurgiQuest filed a motion to dismiss for lack of personal jurisdiction and to dismiss the Minnesota state law claims.

25. On or about March 26, 2014, the Minnesota federal court granted the motion to dismiss for lack of personal jurisdiction.

26. Although the Minnesota lawsuit has ended, Plaintiff has reason to believe that Defendant will re-file its Lanham Act claim in another federal court, such as the District of Delaware, where it is able to obtain personal jurisdiction over Plaintiff.

27. Plaintiff also has reason to believe that Defendant Lexion has made and continues to make these and other similar statements to SurgiQuest's customers, potential customers, and those with whom it does business or plans to do business.

28. Plaintiff thus seeks a declaratory judgment that its conduct in marketing, providing and selling the AirSeal® system, does not violate the Lanham Act.

Lexion's False and Misleading Advertising

29. Defendant markets its devices primarily on the premise that they heat and humidify insufflation gas to 95˚ F and 95% humidity, which it calls "conditioning" the insufflation gas, that conditioning is supposedly scientifically proven to reduce certain side effects of laparoscopic surgery, and that as a result, surgeries utilizing Lexion's devices supposedly result in patients purportedly experiencing less post-operative pain.

30. The "research" on which Defendant bases this claim was initially conducted by Defendant's own Chief Medical Officer, Dr. Douglas E. Ott.

31. Dr. Ott is a convicted felon.

32. Dr. Ott's license to practice medicine was suspended in Ohio for ten years, and he was sanctioned in Indiana as a result of convictions for Medicaid fraud in Kentucky and Indiana.

33. Dr. Ott's "flagship" paper titled Reduction of Laparoscopic-Induced Hypothermia, Postoperative Pain and Recovery Room Length of Stay By Pre-Conditioning Gas With The Insuflow® Device: A Prospective Randomized Controlled Multi-Center Study (1999) was published in a journal - the Journal of the Society of Laparoendoscopic Surgeons - on whose editorial review board Dr. Ott sits.

34. The "study" presented little data and no statistics, making it unverifiable.

35. Indeed, Dr. Ott's "research" has been criticized for its lack of verifiable data, and subsequent research indicates that his claims are both controversial and unproven.

36. For example, an article by Nguyen, et al. titled Invited Commentary, Is Heated and Humidified Gas Necessary During Laparoscopic Gastric Bypass?, 15 Obes. Surg. 73, 73-74 (2005) notes that "[n]o subsequent clinical trials . . . have replicated [Dr. Ott's] findings" and that "the preponderance of data from current literature do not support the clinical use of heated and humidified gas during complex laparoscopic operations."

37. An article by Farley, et al. titled Double-Blind, Prospective, Randomized Study of Warmed, Humidified Carbon Dioxide Insufflation vs. Standard Carbon Dioxide for Patients Undergoing Laparoscopic Cholecystectomy, 139 Arch. Surg. 739, 739, 742-44 (2004), conducted by the Mayo Clinic, concluded that heating and humidifying with Lexion's Insuflow device produced "no major clinically relevant differences" compared to covering the patient with

a heating blanket (739, 742), which is now the standard of care. It also noted that its authors could not replicate Dr. Ott's results (742). Following the article is invited commentary in which Dr. Thomas R. Huntington notes that Dr. Ott's study "would not pass peer review in this day and age" and that "his results are thermodynamically impossible."

38. An article by Champion, et al. titled Prospective Randomized Trial of Heated Humidified Versus Cold Dry Carbon Dioxide Insufflation During Laparoscopic Gastric Bypass, 2 Surg. Obes. Relat. Dis. 445, 448 (2006) notes that the first reports touting the benefits of heated, humidified insufflation gas "were from Ott, and his results have not been reproduced by other investigators, which raised debate over his outcomes" and that the author's own study "which involved 50 patients . . . failed to convincingly demonstrate a clinically significant benefit."

39. An article by Neudecker, et al. titled The European Association for Endoscopic Surgery Clinical Practice Guideline on the Pneumoperitoneum for Laparoscopic Surgery, 16 Surg. Endosc. 1121, 1121 (2002) notes that "[t]he clinical benefits of warmed, humidified insufflation gas are minor and contradictory."

40. Finally, an article by Davis, et al. titled Heating and Humidifying of Carbon Dioxide During Pneumoperitoneum is not Indicated: A Prospective Randomized Trial, 20 Surg. Endosc. 153, 153 (2006) concluded that "[h]eating and humidifying of CO2 is not justified for patients undergoing laparoscopic bariatric surgery."

41. The above are only a sampling of the myriad articles that note the controversy or inaccuracy of the claimed benefits of Defendant's Insuflow product.

42. Defendant Lexion has made and continues to make false and misleading representations concerning its product in its advertising materials and promotional efforts

throughout the United States, and upon information and belief in Delaware. Such misrepresentations include that Defendant's devices are the only products on the market that effectively reduce side effects allegedly because they are the only products that actively heat and humidify insufflation gas.

43. The false and misleading representations that Lexion makes on its website (which provides summaries of "scientific" articles) or in its marketing materials about its Insuflow device or about the studies it claims support use of the device include, but are not limited to:

Lexion's Representations	**Why They Are False or Misleading**
The study conducted at Maimonides Medical Center by Bala, et al. in 2004 concluded that "Patients who received warm humidified carbon dioxide (Insu*flow*® device) during laparoscopic roux-en-y gastric bypass surgery for morbid obesity required significantly less post-operative analgesia than those who did not."	(1) The study actually concluded that "The use of warmed, humidified CO2 insufflation in bariatric patients undergoing LRYGBP was not associated with any significant benefit with regards to post-operative pain." (emphasis added). Lexion's false representation that the study had a completely opposite conclusion misleads consumers into believing that use of its product has benefits when it was not found to have such benefits.
The Insuflow is "proven technology shown to consistently reduce or eliminate" shoulder pain. (This advertisement is annexed hereto as **Exhibit C**.)	(1) SurgiQuest is aware of no studies that conclude that the Insuflow is capable of eliminating shoulder pain. (2) The data supporting Lexion's claim that heating and humidifying insufflation gas reduces side effects (the "proven technology") is controversial and unproven.
The article by Hamza, et al. titled Heated and Humidified Insufflation During Laparoscopic Gastric Bypass Surgery: Effect on Temperature, Postoperative Pain, and Recovery Outcomes (2005) reported results that: "Use of the Insu*flow*® device had 1) statistically significant higher intraoperative core body temperature, 2) no post-operative shivering, 3) less post-operative morphine analgesia, and 4) a higher quality of recovery by post-operative	(1) This article is of questionable reliability given that it was funded by Lexion and that the authors did not control for the standard of care (which requires protecting the patient with an "active warming device," i.e. a heating blanket). Also, Lexion does not disclose its financial support of the article on its website, which misleads consumers into believing that the article is independent and reliable. (2) The "statistically significant" difference in core body temperature is only 1° C, meaning that it has no clinical relevance. Failure to include the actual difference misleads consumers into believing that the

day two."	study actually found clinical value when it did not. (3) "No post-operative shivering" is misleading to consumers because only four patients experienced shivering in the control group. (4) "A higher quality of recovery by post-operative day two" misleads consumers into believing that improved recovery persisted past post-operative day two, whereas the study indicates that improved recovery was only present on post-operative day two.
The article by Mouton, et al. titled A Randomized Controlled Trial Assessing the Benefit of Humidified Insufflation Gas During Laparoscopic Surgery (1999) concluded that "The use of humidified insufflation gas reduces post-operative pain following laparoscopic cholecystectomy."	The article's conclusion did not end there; it went on to state that "but except for these relatively brief procedures the heat preserving effect of humidified insufflation is not significant." (emphasis added). Omitting the second half of the article's conclusion misleads customers into believing that the purported reduction in pain was statistically significant and/or clinically relevant when the article found that it was not.
The article by Farley, et al. titled Double Blind, Prospective, Randomized Study of Warmed Humidified Co2 for Patients Undergoing Laparoscopic Cholecystectomy (3004) comments that "The statistically significant findings were 4-fold: patients were warmer intraoperatively using the Insu*flow*® device, they harbored less shoulder pain at PACU entry, they had less abdominal pain at 2 weeks post-operatively, and they used less pain medication at 2 weeks post-operatively."	Lexion omits the conclusion of the study, which was that despite a finding of statistical significance, "no major clinically relevant differences" were found. This omission misleads consumers into believing that the study - conducted at the Mayo Clinic - found use of the Insuflow to have clinical relevance when it did not.
The article by Almeida titled Awake Microlapsy with the Insuflow® Device (2002) concluded that "Heating and humidifying the carbon dioxide gas produced fewer patient complaints of shoulder pain and shivering and decreased fogging of the microlaparoscope lens compared with procedures done with dry carbon dioxide."	(1) Lexion failed to disclose that this article was published in a journal for which its own chief medical officer sits on the editorial review board - misleading consumers into believing that the article is independent when, upon information and belief, it was not. (2) Lexion failed to disclose that the paper reported no statistical significance in its findings, misleading consumers to believe that the reported results were statistically significant and/or clinically relevant.

The article by Demco titled The Effect of Heating and Humidifying Gas on Patients Undergoing Awake Laparoscopy developed circa 2000 found that 80% of patients undergoing a procedure with the Insuflow left the hospital within 90 minutes, and concluded that "Heating and humidifying CO2 increases patient tolerance during awake laparoscopy using local anesthesia, decreases the frequency and duration of shoulder pain, shortens recovery time and improves safety of the procedure."	(1) The article found that 70% of patients - not 80% - were discharged within 90 minutes. (2) Lexion failed to report that the study found none of its results to be statistically significant (never mind clinically relevant), misleading consumers into believing that the study has clinical or scientific value, when it does not.

44. Upon information and belief, Defendant has made and continues to make these false and misleading representations about its product even though it knows that the "research" supporting its claims is unproven and controversial.

45. Defendant has also made false and misleading representations about Plaintiff's AirSeal® system. For example, Defendant has produced a memorandum dated March 5, 2015, entitled "New Testing on SurgiQuest® AirSeal® Equipment," signed by Defendant's Chief Executive Officer, Patrick Spearman (the "AirSeal® Memo"). Upon information and belief, Defendant sent the AirSeal® Memo to Plaintiff's customers and prospective customers.

46. The AirSeal® Memo falsely claims that the AirSeal® system puts patients at risk by introducing unfiltered air into the patient's abdomen. Upon information and belief, as alleged support for this false and defamatory statement, Defendant attached to the AirSeal® Memo two test reports that Defendant commissioned on the AirSeal® system. Upon information and belief, Defendant knew that its testing was unreliable because it lacked proper controls, utilized flawed methodology, and was susceptible to experimenter bias. Nonetheless, Defendant made

numerous false and misleading statements about what these test reports purport to show, including:

> (1) "Based on the results of these tests, when the AirSeal® System is used in a typical laparoscopic surgery . . . there is a high probability that a substantial or significant amount of unfiltered room air will be delivered to the patient's abdomen by the AirSeal® equipment.
>
> (2) "The attached test reports and the experiments reported therein establish that the AirSeal® product causes unfiltered room air to enter the patient's abdomen under leak conditions that occur in many laparoscopic surgeries."
>
> (3) "The test results of two laboratories indicate that under leak conditions not uncommon during laparoscopic surgery **the AirSeal® equipment may cause air to be present in the abdomen in amounts as high as 20%, 40%, 50% and even above 60% in some surgical type applications**[.]"
>
> (4) "All patients, doctors, nurses and hospitals are taking on added risk when the AirSeal® equipment is used in a procedure with leaks on the order of those reported in the testing."

47. As of September 30, 2015, more than 1,600 AirSeal® systems were deployed in over 700 institutions worldwide. Upon information and belief, AirSeal® disposable devices have been used in more than 340,000 surgical procedures worldwide since 2011. Upon information and belief, there have been no reported incidents in which the AirSeal® system caused or contributed to a death or serious injury.

48. Upon information and belief, Defendant has made and continues to make false and misleading representations about Plaintiff's AirSeal® system even though it knows that the testing supporting its claims is unreliable and misleading.

49. As an additional example, Defendant has produced a chart entitled "System Impact on Complication Rates Comparative and Total" (the "Comparative Chart") which purports to show complication rates between Plaintiff's AirSeal® system and conventional

trocars. Upon information and belief, Defendant and sales representatives working for Defendant sent the Comparative Chart to Plaintiff's customers and prospective customers, along with statements falsely and misleadingly characterizing the data as showing increased complications and increased risks with Plaintiff's AirSeal® system.

50. Upon information and belief, Defendant knew that its comparative methodology was biased because it selected only a subset of data for the comparison, lacked proper controls, utilized flawed methodology, and was susceptible to bias by the drafters, including Defendant's Chief Medical Officer Dr. Douglas Ott.

51. Upon information and belief, Defendant has made and continues to make these false and misleading representations about Plaintiff's AirSeal® system even though it knows that the Comparative Chart and characterizations thereof are unreliable and misleading.

COUNT I
Violation of Section 43(a) of The Lanham Act, 15 U.S.C. § 1125(a)

52. Plaintiff realleges and incorporates each of the foregoing paragraphs of the complaint.

53. Defendant's false and misleading advertisements and oral statements constitute false advertising in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

54. Section 1125(a)(1)(A) and (B) of the Lanham Act provide, in pertinent part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> > (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection or association of such person with another person, or as to the origin,

> sponsorship, or approval of his or her goods, services or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities . . .

55. Defendant has made false statements of fact about its own product in its advertisements, marketing materials, and/or oral statements, as described herein, with the intent to mislead and deceive consumers.

56. Defendant has made false and misleading statements of fact about Plaintiff's AirSeal® system in its advertisements, marketing materials, and/or oral statements, as described herein, with the intent to mislead and deceive consumers.

57. Upon information and belief, Defendant's false statements of fact have actually deceived or tended to deceive a substantial segment of the relevant consumers for laparoscopic surgery devices.

58. Upon information and belief, Defendant's false statements of fact have influenced the buying decisions of consumers for laparoscopic surgery devices throughout the United States.

59. Defendant's false and misleading statements of fact were and are made in interstate commerce.

60. Defendant's improper activities, as described herein, have been willful and deliberate, thereby making this an exceptional case under the Lanham Act. Indeed, Defendant knew or reasonably should have known that its advertisements and marketing material were false and misleading. Therefore, Defendant's false advertising of its products was purposeful and knowing and merits a finding that exceptional circumstances exist sufficient to support an award of attorneys' fees and treble damages.

61. Defendant's unlawful actions have caused, and will continue to cause, Plaintiff irreparable harm unless enjoined.

62. Defendant has profited from its unlawful actions and has been unjustly enriched to the detriment of Plaintiff. Defendant's unlawful actions have caused Plaintiff monetary damage in an amount presently unknown, but in an amount to be determined at trial.

COUNT II
Declaratory Judgment

63. Plaintiff realleges and incorporates each of the foregoing paragraphs of the complaint.

64. Plaintiff seeks this Court's determination, pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, concerning Plaintiff's right to continue its lawful conduct in marketing and advertising its AirSeal® product.

65. An actual and justiciable controversy exists between Plaintiff and Defendant with respect to the matters set forth herein, as to which Plaintiff is entitled to have a declaration of its rights and further relief as this Court finds necessary and appropriate.

66. Plaintiff's promotion, marketing and sale of its AirSeal® system does not violate the Lanham Act in any way. Indeed, Plaintiff does not mention Defendant or Defendants' products in its advertising materials or in its promotional and marketing efforts, and Plaintiff does not misrepresent its own products.

67. Despite Plaintiff's lawful conduct, Defendant has engaged in litigation and other acts for the purpose of interfering with Plaintiff's business and obtaining a competitive advantage thereby.

68. By reason of the foregoing, Plaintiff is entitled to have a judgment entered declaring that Plaintiff has not violated the Lanham Act in connection with its promotion, marketing, advertising and sales of the AirSeal® system.

COUNT III
Delaware Deceptive Trade Practices Act
Del. Code Ann. Tit. 6 § 2531 et. seq.

69. Plaintiff realleges and incorporates each of the foregoing paragraphs of the complaint.

70. Defendant's advertising and promotional materials, as described herein, contain literally false statements regarding the nature, characteristics, benefits, uses or qualities of goods in commerce.

71. Defendant's advertising and promotional materials, as described herein, contain literally false representations of fact of the goods of another.

72. Defendant's advertising and promotional materials, as described herein, create a likelihood of confusion and misunderstanding.

73. These literally false advertising and promotional statements are material to consumer purchasing decisions, and have caused and are causing actual consumer confusion and damages to Plaintiff.

74. Defendant's false statements and advertising violate the Delaware Deceptive Trade Practices Act and the common law of Delaware.

75. Unless this Court enjoins Defendant from continuing to make these false claims and orders their retraction and/or correction, the false advertising will continue to cause Plaintiff to suffer a loss of consumer confidence, sales, profits, and goodwill, which will irreparably harm Plaintiff.

76. Defendant's false statements are willful, with malicious and deceptive intent, making this an exceptional case.

77. Plaintiff has no adequate remedy at law.

COUNT IV
Common Law Unfair Competition

78. Plaintiff realleges and incorporates each of the foregoing paragraphs of the complaint.

79. Defendant's unlawful acts, as described above, constitute unfair competition under Delaware law.

80. By making false and misleading statements about its own product, Defendant has utilized unfair methods of competition and deceptive trade practices.

81. By making false and misleading statements about Plaintiff's AirSeal® System, Defendant has utilized unfair methods of competition and deceptive trade practices.

82. Defendant engaged in such misrepresentations with malicious intent.

83. Defendant's unlawful actions have caused, and will continue to cause, Plaintiff irreparable harm to its business and reputation unless enjoined.

84. Defendant has also profited from its unlawful actions and has been unjustly enriched to the detriment of Plaintiff. Defendant's unlawful actions have caused Plaintiff monetary damage in an amount presently unknown, but to be determined at trial.

CONCLUSION

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment:

1. In favor of Plaintiff and against Defendant on all of Plaintiff's claims;

2. Enjoining and restraining Defendant, its officers, directors, advisory board members, clinical advisory board members, robotic advisory board members, scientific advisory

board members, agents, servants, employees, attorneys, and all others in active concert or participation with Defendant, during the pendency of this action and thereafter permanently from:

A. Unfairly competing with Plaintiff in any manner whatsoever;

B. Engaging in any deceptive trade practice with respect to Plaintiff or Plaintiff's AirSeal® system in any manner whatsoever;

C. Engaging in any false advertising with respect to Plaintiff, Plaintiff's AirSeal® system, and Defendant's Insuflow® or Synergy ® device and any related goods or services in any manner whatsoever; and

D. Disparaging Plaintiff's AirSeal® system in any manner whatsoever;

3. Requiring Defendant to deliver up, or cause to be delivered up, for destruction all advertisements, marketing material, and all other materials in the possession or control of Defendant that contain any false statements of fact about its Insuflow device and any related goods or services, Plaintiff, and Plaintiff's AirSeal® device;

4. Requiring Defendant to account for and pay over to Plaintiff the amount of Plaintiff's damages pursuant to 15 U.S.C. § 1117 and Delaware law;

5. Requiring Defendant to account for and pay over to Plaintiff the amount of Defendant's profits pursuant to 15 U.S.C. § 1117 and Delaware law;

6. Requiring Defendant to account for and pay over to Plaintiff the costs of the action pursuant to 15 U.S.C. § 1117 and Delaware law;

7. Trebling any damage award pursuant to 15 U.S.C. § 1117 and Delaware law;

8. Finding this case exceptional and requiring Defendant to pay over to Plaintiff its attorneys' fees incurred in connection with this case pursuant to 15 U.S.C. § 1117 and Delaware law;

9. Declaring that Plaintiff's conduct in marketing its AirSeal® device does not violate the Lanham Act and is otherwise not false or misleading;

10. Awarding Plaintiff such other relief in its favor as the Court may deem just and equitable.

JURY DEMAND

Plaintiff demands trial of its claims for relief herein before a jury.

Dated: May 3, 2016

DLA PIPER LLP (US)

/s/ Denise S. Kraft

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